



VIRGINIA DEPARTMENT OF
SOCIAL SERVICES



Assisted Living Facility COVID-19 Webinar Series

Episode Three: COVID-19 Infection Control Update

May 27, 2021

12:00 p.m.–1:00 p.m.

Agenda

12:00 – 12:05: Welcome

12:05 – 12:15: COVID-19 “At-Home” Testing and CLIA Best Practices

Debra Hopkins; VDH Office of Licensure and Certification (OLC) & Healthcare-Associated Infections (HAI) Team

12:15 – 12:20: Q&A for COVID-19 “At-Home” Testing and CLIA Best Practices

12:20 – 12:45: COVID-19 Infection Control Update

Dr. Rehab Abdelfattah, MD, MPH, CIC; VDH Healthcare-Associated Infections (HAI) Team

Lisa Sollot; VDH Healthcare-Associated Infections (HAI) Team

12:45 – 12:55: Q&A for COVID-19 Infection Control Update

12:55 – 1:00: Instant Poll

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CLIA

Clinical Laboratory Improvement Amendment

-A Federal regulatory program ensuring quality lab testing, enforced by CMS and administrated in Virginia by VDH OLC.

Facilities that examine human specimens for the diagnosis, prevention or treatment of any disease, or health assessment of human beings is considered a laboratory and must meet CLIA requirements. These facilities must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed.

COVID tests and Home Use Authorization:

A CLIA Certificate is not required of individuals self-collecting swabs and performing these at-home COVID test when in their private residence.

These same tests when used in a patient care setting, require a CLIA Certificate of Waiver.

*A **CLIA Certificate of Waiver** is a type of certificate issued by CLIA. Facilities that have a CLIA Certificate of Waiver can perform tests that are classified as CLIA Waived by the FDA or have a FDA EUA for a waived testing environment.*

Do I already have a CLIA Certificate?

CMS CLIA lab look up at: <https://qcor.cms.gov/main.jsp>

How do I apply for a CLIA Certificate?

CMS 116: CLIA Application for Certification

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)
APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

- ☐ Initial Application ☐ Survey
☐ Change in Certificate Type
☐ Other Changes (Specify) _____

Effective Date _____

CLIA IDENTIFICATION NUMBER

_____ D _____

(If an initial application leave blank, a number will be assigned)

FACILITY NAME

FEDERAL TAX IDENTIFICATION NUMBER

EMAIL ADDRESS

TELEPHONE NO. (Include area code)

FAX NO. (Include area code)

FACILITY ADDRESS — Physical Location of Laboratory (Building, Floor, Suite
if applicable.) Fee Coupon/Certificate will be mailed to this Address unless
mailing or corporate address is specifiedMAILING/BILLING ADDRESS (If different from facility address) send Fee Coupon
or certificate

NUMBER, STREET (No P.O. Boxes)

NUMBER, STREET

CITY

STATE

ZIP CODE

CITY

STATE

ZIP CODE

SEND FEE COUPON TO THIS ADDRESS

- ☐ Physical
☐ Mailing
☐ Corporate

SEND CERTIFICATE TO THIS ADDRESS

- ☐ Physical
☐ Mailing
☐ Corporate

CORPORATE ADDRESS (If different from facility) send Fee Coupon or certificate

NUMBER, STREET

NAME OF DIRECTOR (Last, First, Middle Initial)

CITY

STATE

ZIP CODE

CREDENTIALS

FOR OFFICE USE ONLY

Date Received

II. TYPE OF CERTIFICATE REQUESTED (Check only one) Please refer to the accompanying instructions for inspection and
certificate testing requirements

- ☐ Certificate of Waiver (Complete Sections I – VI and IX – X)
☐ Certificate for Provider Performed Microscopy Procedures (PPM) ((Complete Sections I-VII and IX-X)
☐ Certificate of Compliance (Complete Sections I – X)
☐ Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your
laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes.
☐ The Joint Commission ☐ AOA ☐ AABB ☐ A2LA
☐ CAP ☐ COLA ☐ ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an
approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within
11 months after receipt of your Certificate of Registration.

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and
experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted
with this application.

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control
number. The valid OMB control number for this information collection is 0938-0581. Expiration Date: 3/31/2021. The time required to complete this information
collection is estimated to average one hour per response, including the time to review instructions, search existing data resources, gather the data needed,
and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this
form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. *****CMS
Disclaimer*****Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports
Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number
listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact
LabExcellence@cms.hhs.gov.

III. TYPE OF LABORATORY (Check the one most descriptive of facility type)

- | | | |
|---|---|---|
| <input type="checkbox"/> 01 Ambulance | <input type="checkbox"/> 11 Health Main. Organization | <input type="checkbox"/> 22 Practitioner Other (Specify) |
| <input type="checkbox"/> 02 Ambulatory Surgery Center | <input type="checkbox"/> 12 Home Health Agency | |
| <input type="checkbox"/> 03 Ancillary Testing Site in
Health Care Facility | <input type="checkbox"/> 13 Hospice | |
| <input type="checkbox"/> 04 Assisted Living Facility | <input type="checkbox"/> 14 Hospital | <input type="checkbox"/> 23 Prison |
| <input type="checkbox"/> 05 Blood Bank | <input type="checkbox"/> 15 Independent | <input type="checkbox"/> 24 Public Health Laboratories |
| <input type="checkbox"/> 06 Community Clinic | <input type="checkbox"/> 16 Industrial | <input type="checkbox"/> 25 Rural Health Clinic |
| <input type="checkbox"/> 07 Comp. Outpatient Rehab Facility | <input type="checkbox"/> 17 Insurance | <input type="checkbox"/> 26 School/Student Health Service |
| <input type="checkbox"/> 08 End Stage Renal Disease
Dialysis Facility | <input type="checkbox"/> 18 Intermediate Care Facilities for
Individuals with Intellectual
Disabilities | <input type="checkbox"/> 27 Skilled Nursing Facility/
Nursing Facility |
| <input type="checkbox"/> 09 Federally Qualified
Health Center | <input type="checkbox"/> 19 Mobile Laboratory | <input type="checkbox"/> 28 Tissue Bank/Repositories |
| <input type="checkbox"/> 10 Health Fair | <input type="checkbox"/> 20 Pharmacy | <input type="checkbox"/> 29 Other (Specify) |
| | <input type="checkbox"/> 21 Physician Office | |

IV. HOURS OF LABORATORY TESTING (List times during which laboratory testing is performed in HH:MM format) If testing 24/7 Check Here ☐

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:							
TO:							

(For multiple sites, attach the additional information using the same format.)

V. MULTIPLE SITES (must meet one of the regulatory exceptions to apply for this provision in 1-3 below)

Are you applying for a single site CLIA certificate to cover multiple testing locations?

- ☐ No. If no, go to section VI. ☐ Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

- Is this a laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site, such as
mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations, and may be covered
under the certificate of the designated primary site or home base, using its address?
☐ Yes ☐ No
If yes and a mobile unit is providing the laboratory testing, record the vehicle identification number(s) (VINs) and attach to the
application.
- Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15
moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for
multiple sites?
☐ Yes ☐ No
If yes, provide the number of sites under the certificate _____ and list name, address and test performed for each
site below.
- Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical
location or street address and under common direction that is filing for a single certificate for these locations?
☐ Yes ☐ No
If yes, provide the number of sites under this certificate _____ and list name or department, location within
hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here ☐ and attach the additional information using the same format.

NAME AND ADDRESS/LOCATION	TESTS PERFORMED/SPECIALTY/SUBSPECIALTY
NAME OF LABORATORY OR HOSPITAL DEPARTMENT	
ADDRESS/LOCATION (Number, Street, Location if applicable)	
CITY, STATE, ZIP CODE	TELEPHONE NO. (Include area code)
NAME OF LABORATORY OR HOSPITAL DEPARTMENT	
ADDRESS/LOCATION (Number, Street, Location if applicable)	
CITY, STATE, ZIP CODE	TELEPHONE NO. (Include area code)

In the next three sections, indicate testing performed and annual test volume.

VI. WAIVED TESTING If *only* applying for a Certificate of Waiver, complete this section and skip sections VII (PPM Testing) and VIII (Non-Waived Testing).

Identify the **waived testing (to be) performed**. Be as specific as possible. This includes each analyte **test system or device used** in the laboratory.

e.g. (Rapid Strep, Acme Home Glucose Meter)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all waived tests performed _____

☐ Check if no waived tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.

VII. PPM TESTING If *only* applying for a Certificate for PPM, complete this section and skip section VIII (Non-Waived Testing).

Identify the PPM testing (to be) performed. Be as specific as possible.

e.g. (Potassium Hydroxide (KOH) Preps, Urine Sediment Examinations)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all PPM tests performed _____

If also performing waived complexity tests, complete Section VI. For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the specialty/subspecialty category and the "total estimated annual test volume" in section VIII.

☐ Check if no PPM tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.

IX. TYPE OF CONTROL (check the one most descriptive of ownership type)

VOLUNTARY NONPROFIT

☐ 01 Religious Affiliation

☐ 02 Private Nonprofit

☐ 03 Other Nonprofit

(Specify)

FOR PROFIT

☐ 04 Proprietary

GOVERNMENT

☐ 05 City

☐ 06 County

☐ 07 State

☐ 08 Federal

☐ 09 Other Government

(Specify)

X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

PRINT NAME OF OWNER/DIRECTOR OF LABORATORY _____

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY (Sign In Ink) _____

DATE _____

NOTE: Completed 116 applications must be sent to your local State Agency. Do not send any payment with your completed 116 application.

STATE AGENCY CONTACT INFORMATION CAN BE FOUND AT:

<http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>

Mail (overnight delivery recommended) the *signed* original CMS116 to our office at:

Virginia Department of Health
Office of Licensure and Certification
9960 Mayland Drive, Suite 401
Henrico, VA 23233-1485

No money is due with the application. Once you get your CLIA number, the \$180 fee can be paid the next day on-line at **pay.gov**

For Waived COVID testing:

Follow Manufacturer Instructions,
Document training,
Document temperature monitoring of kit storage and testing
areas,
Report test results to the VDH or HHS.

CLIA inquiries can be emailed to:
CLIALAB@vdh.virginia.gov

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Infection Control Guidance Updates

The Interim Public Health Recommendations for Fully Vaccinated People, posted May 13, 2021 found [here](#), that fully vaccinated people no longer need to wear a mask or physically distance in any setting,

- ✓ **Do not apply to healthcare settings** - staff, patients, residents, and visitors should continue to wear masks as recommended in all healthcare facilities.
- ✓ **Healthcare settings** refers to places where healthcare is delivered and includes, but is not limited to, acute care facilities, long term acute care facilities, inpatient rehabilitation facilities, nursing homes and assisted living facilities, home healthcare, vehicles where healthcare is delivered (e.g., mobile clinics), and outpatient facilities, such as dialysis centers, physician offices, and others.
- ✓ Healthcare facilities should continue to refer to the Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination for recommendations regarding source control and physical distancing in healthcare settings.

Infection Control Guidance Updates-cont'd.

Highlights from CDC's, Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination, [updated](#) 4/27/2021

Communal Activities and Dining:

- Fully vaccinated patients/residents can participate in communal dining without use of source control or physical distancing.
- If unvaccinated patients/residents are dining in a communal area (e.g., dining room) all patients/residents should use source control when not eating and unvaccinated patients/residents should continue to remain at least 6 feet from others.
- If vaccination status cannot be determined, the safest practice is for all participants to follow all recommended infection prevention and control practices including maintaining physical distancing and wearing source control.

Healthcare Personnel:

In general, fully vaccinated HCP should continue to wear source control while at work. However, fully vaccinated HCP could dine and socialize together in break rooms and conduct in-person meetings without source control or physical distancing. If unvaccinated HCP are present, everyone should wear source control and unvaccinated HCP should physically distance from others.

Infection Control Guidance Updates-cont'd.

Work restriction for asymptomatic HCP and quarantine for asymptomatic patients/residents:

- Fully vaccinated HCP with higher-risk exposures who are asymptomatic do not need to be restricted from work for 14 days following their exposure.

However, HCP who have traveled should continue to follow CDC travel recommendations and requirements

- Fully vaccinated in-patients and residents in healthcare settings should continue to quarantine following prolonged close contact (within 6 feet for a cumulative total of 15 minutes or more over a 24-hour period) with someone with SARS-CoV-2 infection; outpatients should be cared for using recommended Transmission-Based Precautions
- Quarantine is no longer recommended for residents who are being admitted to a post-acute care facility if they are fully vaccinated and have not had prolonged close contact with someone with SARS-CoV-2 infection in the prior 14 days.

Infection Control Guidance Updates-cont'd.

SARS-CoV-2 Testing:

- Anyone with symptoms of COVID-19, regardless of vaccination status, should receive a viral test immediately.
- Asymptomatic HCP with a higher-risk exposure and patients or residents with prolonged close contact with someone with SARS-CoV-2 infection, regardless of vaccination status, should have a series of two viral tests for SARS-CoV-2 infection. In these situations, testing is recommended immediately and 5–7 days after exposure.
- People with SARS-CoV-2 infection in the last 90 days do not need to be tested if they remain asymptomatic, including those with a known contact.
- In healthcare facilities with an outbreak of SARS-CoV-2, recommendations for viral testing HCP, residents, and patients (regardless of vaccination status) remain unchanged.

Infection Control Guidance Updates-cont'd.

What trigger testing in LTCFs?

- 1- When a symptomatic individual is identified: test staff and residents vaccinated and unvaccinated, with signs and symptoms must be tested
- 2- Outbreak: test all staff and residents, vaccinated and unvaccinated, that previously tested negative until no new cases are identified
- 3- Routine testing of asymptomatic HCP (for healthcare facilities that are performing screening testing):
 - unvaccinated HCP should continue expanded screening testing.
 - for asymptomatic HCP who do not have a known exposure, vaccinated HCP can be excluded from such a testing program.

Quarantine Recommendations in Healthcare Settings

HCPs	Patients/Residents
Unvaccinated HCP who have traveled domestically or internationally	Fully vaccinated residents and inpatients in health care setting should continue to quarantine following an exposure to someone with COVID-19
	Unvaccinated residents newly admitted or re-admitted to a post-acute care facility
	For unvaccinated residents leaving the facility for ≥ 24 hours

Quarantine Recommendations in Healthcare Settings- Cont.

- Quarantine is currently not required for residents, regardless of vaccination status, leaving the facility for less than 24 hours who are asymptomatic and have not had close contact with someone infected with SARS-CoV2. However, facilities might consider quarantining residents based on an assessment of risk, uncertainty exists about adherence or adherence of those around them to recommended IPC practices

Visitations Scenarios

Scenario # 1

Residents who are infected with COVID-19 or residents who are in quarantine:

Indoor visitation limited to compassionate care for vaccinated and unvaccinated residents.

Visitations Scenarios-cont.

Scenario # 2

COVID-19 county positivity rate is $>10\%$ and $\leq 70\%$ of residents are fully Vaccinated:

Indoor visitation for unvaccinated residents should be limited solely for compassionate care

Visitations Scenarios-cont.

Scenario # 3

When an outbreak occurs (a single new case of COVID-19 in a HCP or a new facility onset case in a resident):

Facility should immediately begin outbreak testing and suspend all visitation. If the first round of outbreak testing reveals NO additional COVID-19 cases in other areas of the facility visitation can be resumed in areas with NO COVID-19 cases. HOWEVER, the facility should suspend visitation on the affected unit until the facility meets the criteria to discontinue outbreak testing (14 days with no new cases). If new cases are identified on the first round of testing in other areas indoor visitation should be suspended for all residents until the facility meets criteria to discontinue outbreak testing.

Visitations Scenarios-cont.

Scenario # 4

When a resident shares a room:

Visits for residents who share a room should ideally not be conducted in the resident's room.

If in-room visitation must occur an unvaccinated roommate should not be present during the visit.

Residents and visitors should physically distance from other residents and HCP in the facility

Outdoor visitation is preferred even when the resident and visitor are fully vaccinated. Outdoor visits generally pose a lower risk of transmission due to increased space and air flow.

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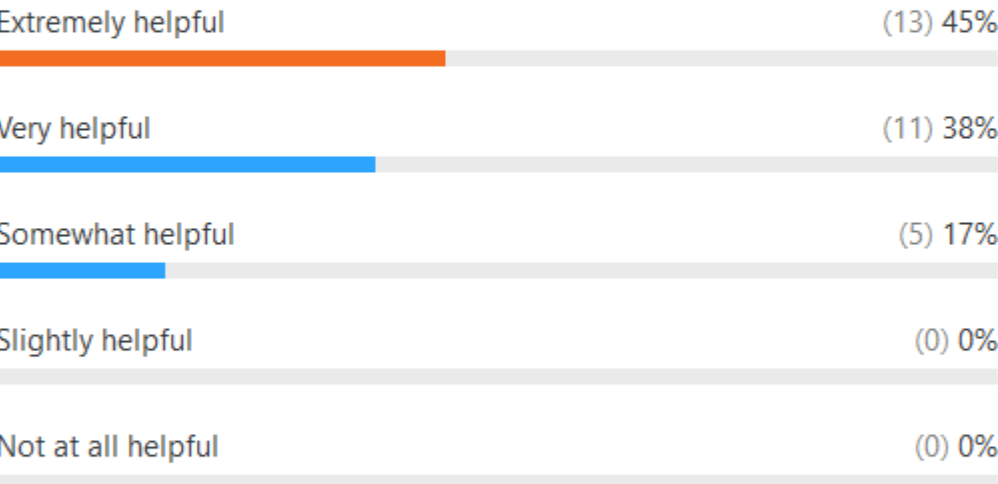
Lisa Sollot; VDH Healthcare-Associated Infections (HAI) Team

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12:55 – 1:00: Instant Poll

Polling is closed
29 voted

1. How helpful was the information presented in this webinar?



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Share Results

Re-launch Polling



City COVID-19 Webinar Series

ode Three: Poll